Docket No. TRNSV-015G

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Joshua Makower, et al.	Group Art Unit: 3738
Serial No.: 09/912,122	Examiner: David Isabella
Filed: July 24, 2001	
For: Catheters and Related Devices for Forming Passageways Between Blood Vessels or Other Anatomical Structures	

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: MAIL STOP APPEAL BRIEF-PATENTS, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on January 18, 2006.

By: _____
Robert D. Buyan

Mail Stop Appeal
Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL

Sir:

Enclosed herewith for filing in relation to the above-identified patent application, please find the following:

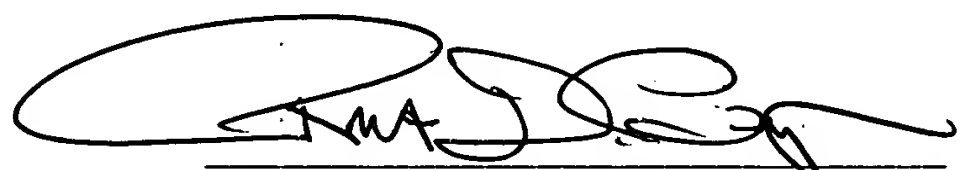
Appeal Brief By Applicant To The Board of Patent Appeals and Interferences;

In accordance with Rule 136, the Commissioner is hereby petitioned for a **four (4)** month extension of time, extending to **January 18, 2006** the period for filing applicant's appeal brief dated July 18, 2006.

The Commissioner is hereby authorized to charge fees due in connection with this filing to Deposit Account No. 50-0878.

Respectfully submitted,
STOUT, UXA, BUYAN & MULLINS, LLP

Dated: January 18, 2006



Robert D. Buyan, Reg. No. 32,460

4 Venture, Suite 300
Irvine, CA 92618
Tel: 949-450-1750
Fax: 949-450-1764
Email: rbuyan@patlaywers.com

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:	
Joshua Makower, et al.	Group Art Unit: 3738
Serial No.: 09/912,122	Examiner: David Isabella
Filed: July 24, 2001	
For: Catheters and Related Devices for Forming Passageways Between Blood Vessels and Other Anatomical Conduits	

MAIL STOP APPEAL BRIEF-PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF BY APPLICANT
TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

Dear Sir:

Applicants, Joshua Makower, et al. (hereafter "Appellant"), have filed a timely notice of Appeal from the final Office Action, dated April 17, 2005 (the "Final Office Action"), rejecting all the claims of the above-identified application. Appellant hereby submits this Brief in support of its appeal.

This Appeal Brief is being filed under the provisions of 37 C.F.R. § 1.192. Appellant hereby petitions for a four (4) month extension of time under 37 C.F.R. §1.136. The Director is authorized to deduct all fees due in connection with this filing from Deposit Account No. 50-0878.

An oral hearing is requested. Appellant will file a separate request for oral hearing along with the required fee within the prescribed time period after submission of the Examiner's answer.

TABLE OF CONTENTS

I. REAL PARTY IN INTEREST 4

II. RELATED APPEALS AND INTERFERENCES 4

III. STATUS OF CLAIMS 4

IV. STATUS OF AMENDMENTS 5

V. SUMMARY OF INVENTION 6

VI. ISSUES PRESENTED 8

VII. GROUPING OF CLAIMS 8

VIII. ARGUMENT 9

IX. CONCLUSION 20

X. APPENDIX OF CLAIMS 21

I. REAL PARTY IN INTEREST

The invention and this patent application are presently assigned to Medtronic Vascular, Inc., which is the real party in interest.

II. RELATED APPEALS AND INTERFERENCES

To the best of Appellant's knowledge, there are no other appeals or interferences related to the present appeal that would directly affect, be directly affected by, or have a bearing on the Board's decision.

III. STATUS OF CLAIMS

Claims 53-58 and 61-63 are pending and are the subject of this appeal. Claim 53 is the sole independent claim.

In the final Office Action, the following grounds for rejection were stated:

- claims 53 and 58 were rejected under 35 U.S.C. 102(b) as being anticipated by United States Patent No. 5,366,490(Edwards, et al.);

- claims 54, 55, 61 and 62 were rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards, et al. in view of United States Patent No. 5,331,947(Shturman);

- claims 56 and 57 were rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. in view of Shturman and further in view of United States Patent No. 6,010,480 (Abele et al.); and

- claim 63 was rejected were rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. in view of Shturman and further in view of United States Patent No. 5,345,940 (Seward et al.)

IV. STATUS OF AMENDMENTS

A response to the Final Office Action was filed on May 17, 2005. This response did not include any amendment to the claims. It did, however, included an amendment to the specification inserting corrected language into the "Related Applications" section.

On June 8, 2005 an Advisory Action was issued indicating that Appellants' arguments relating to allowability of the claims were not found to be persuasive. The Advisory Action does not mention the amendment to the specification. Given that this amendment merely inserted corrected language into the "Related Applications" section of the specification and the Advisory Action did not state that such amendment had not been entered, it is presumed that this specification amendment was in fact entered.

V. SUMMARY OF INVENTION

The basic elements of the claimed invention may be appreciated from the example shown in Appellant's Figure 3, as reproduced below:

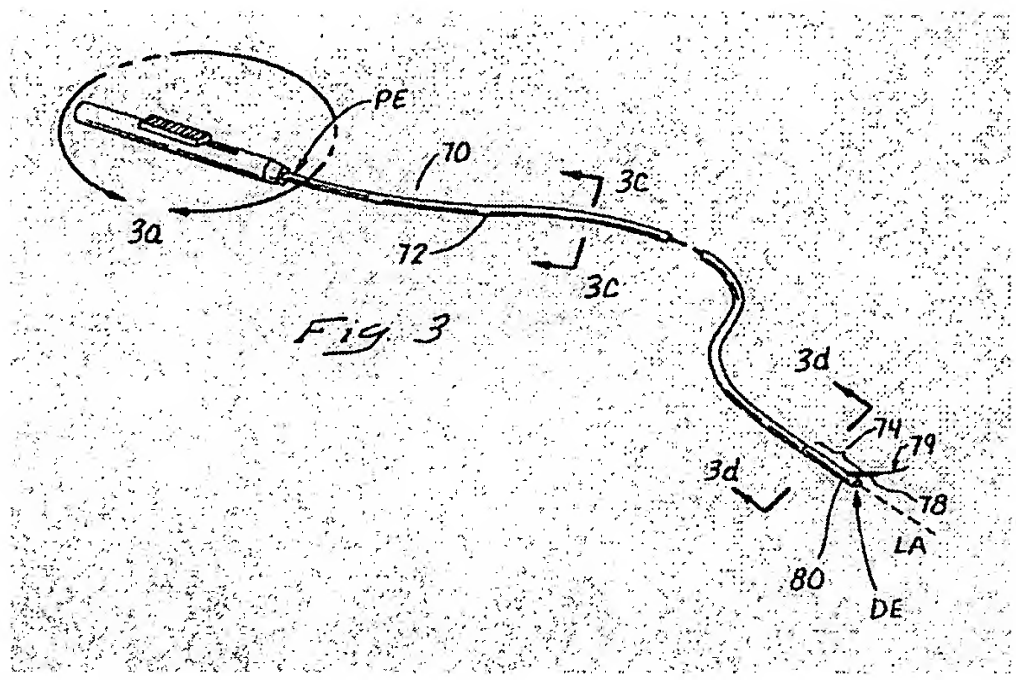


Fig 3

As seen in Figure 3, the claimed system generally comprises a catheter device 70 and a guidewire 79. The catheter device 70 includes an elongate catheter body 72 that is advanceable into a blood vessel lumen. A tissue penetrating element 78 is advanceable out of and retractable back into an opening formed in the side of the catheter body 72. This tissue penetrating element 78 includes a lumen (see cross sections in Figures 3C and 3D), a tissue penetrating distal tip and a distal end opening. The tissue penetrating element 78 is alternately disposable in a first position (e.g., a retracted position) wherein it is substantially within the catheter body 72 and a second position (e.g., as seen in Figure 3 above) wherein the tissue penetrating element extends out of the opening in the catheter body 72 and assumes a predetermined curved configuration. As the hollow penetrating element 72 is

advanced, it penetrates the wall of the blood vessel in which the catheter is inserted, thereby forming a passageway (e.g., a penetration tract) out of that blood vessel lumen. After the hollow penetrating element 78 has been advanced to a desired target location, the guidewire 79 is then advanceable through the lumen of the tissue penetrating element 78 and out of its open distal end as seen in Figure 3 above). Thereafter, as described in Appellants' specification (including page 19, lines 21-29) the penetrating element 78 is retracted back into the catheter body 72 and the catheter device 70 is removed, leaving the guidewire 79 in place to guide other devices or operative instruments to the target location through the passageway (e.g., penetration tract) that was created by advancement of the tissue penetrating element 78.

In some embodiments, the catheter device may incorporate an anchoring member, such as a balloon, for anchoring the catheter body 72 in a desired position within the blood vessel lumen. Such anchoring member may, in some embodiments, have a friction enhancing texture on its surface.

Also, in some embodiments, the catheter body 72 may include a lumen into which an imaging apparatus may be inserted. Such imaging apparatus may then be used to image portions of the device and/or the surrounding anatomy. As explained in the specification, such imaging capability may enable the operator to pre-osition and rotationally orient the catheter body to ensure that the penetrating element 78 will advance to the intended target location and not some other non-intended location.

VI. ISSUES PRESENTED

A. Whether the rejection of claims 53 and 58 under 35 U.S.C. 102(b) as being anticipated by United States Patent No. 5,366,490(Edwards) is proper and sustanable;

B. Whether the rejection of claims 54, 55, 61 and 62 under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. in view of Shturman is proper and sustanable;

C. Whether the rejection of claims 56 and 57 under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. in view of Shturman and further in view of Abele et al. is proper and sustanable; and

D. Whether the rejection of claim 63 under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. in view of Shturman and further in view of Seward et al. is proper and sustainable.

VII. GROUPING OF CLAIMS

For the purposes of this appeal, the claims are grouped as follows:

A. Each of claims 53, 54, 55, 58, and 63 stands or falls alone;

B. Claims 61 and 62 stand or fall together; and

C. Claims 56 and 57 stand or fall together.

VIII. ARGUMENTS

A. The Rejection of Claim 53 is improper and not sustainable

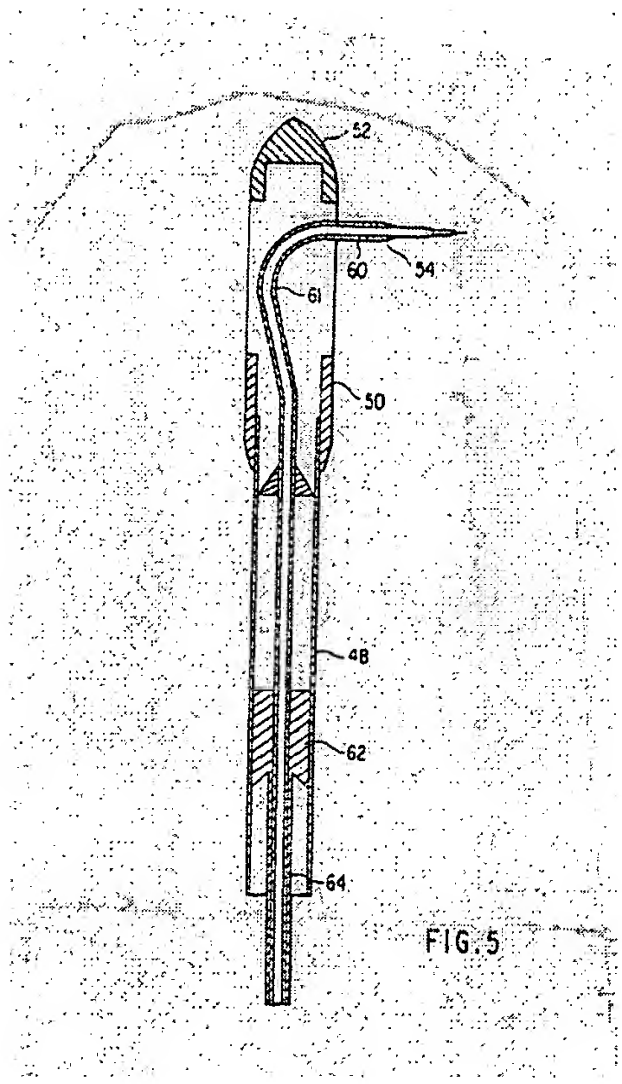
Independent claim 53 is clearly not anticipated by Edwards et al. and is patentably distinguishable over all of the cited prior art.

As presently amended, claim 53 reads as follows:

> *53. A system that is useable to guide the advancement of a guidewire from a location within the lumen of a blood vessel to a location within or outside of the wall of that blood vessel, said system comprising:*
>
> *a elongate catheter body that is advanceable into said blood vessel lumen, said catheter body having at least one lumen extending longitudinally therethrough; an opening formed in said catheter body;*
>
> *a tissue penetrating element having a lumen, a tissue penetrating distal tip and a distal end opening, said tissue penetrating element being alternately disposable in;*
>
> *(a) a first position wherein the tissue penetrating element is substantially within the catheter body; and*
>
> *(b) a second position wherein the tissue penetrating element assumes a predetermined curved configuration and extends out of the opening so as to penetrate a wall of the blood vessel adjacent to the blood vessel lumen in which the catheter is positioned; and*
>
> *a guidewire that is advanceable through the lumen of*

the tissue penetrating element while the tissue penetrating element is in the second position.

In contrast, Edwards, et al. discloses devices that are used to deliver energy (e.g., microwave energy) into the prostate gland to treat prostatic enlargement. Figure 5 of Edwards, et al. is reproduced below:



In general, Edwards, et al. describes probes that are insertable into the urethra and from which a stylet (e.g., item 54 on Figure 5) is advanceable into the prostate gland. The stylet may be electrically conductive and may be surrounded by an insulating sheath (e.g., item 60 on Figure 5 above). Energy (e.g., radiofrequency current)is then delivered into the prostate gland

causing it to shrink.

Appellants' claim 53 specifically recites "a tissue penetrating element having a lumen, a tissue penetrating distal tip and a distal end opening" and "a guidewire that is advanceable through the lumen of the tissue penetrating element while the tissue penetrating element is in the second position."

In the final office action, the Examiner contends that a "tubular member (138, 72 or 60) having a lumen and a distal end opening" disclosed by Edwards et al. satisfies the requirement of "a tissue penetrating element having a lumen, a tissue penetrating distal tip and a distal end opening" recited in independent claim 53. Applicant respectfully disagrees with this reasoning.

In reality, the items designated by Edwards, et al. reference numerals 138, 72 and 60 are clearly not tissue penetrating elements that have lumens, tissue penetrating distal tips and distal end openings. In fact, reference numeral 138 does not refer to a physical component of the device, but rather refers to a "dotted line path" over which a "stylet can be advanced." (col. 8, lines 43-44) This "stylet" is indicated by reference numeral 132. Even if the stylet 132 were properly referred to as a tissue penetrating element, this simple fact is that Edwards, et al. makes no disclosure of any guidewire that is insertable through the stylet and out of its distal end after the stylet has been advanced to the target location, as recited in Appellants' independent claim 53.

Reference numeral 72 of Edwards et al. refers to an insulating sleeve or coating that encloses a "wire mesh or tube 68." Edwards

et al. does not disclose or even suggest the possibility of any tissue penetrating distal tip on either the "insulating sleeve or coating 72" or the "wire mesh or tube 68" that it surrounds. Thus, neither the "insulating sleeve or coating 72" nor the "wire mesh or tube 68" that it surrounds can possibly satisfy the claimed limitation of "a tissue penetrating element having a lumen, a tissue penetrating distal tip and a distal end opening." Moreover, there would be no reason or motivation to modify them to penetrate into tissue, as it is the stylet 132 that performs the tissue penetrating function.

Reference numeral 60 of Edwards et al. refers to a sleeve which encloses a tube 58. Neither the sleeve 60 nor the tube 58 are described as having any tissue penetrating distal tip as required by applicant's claim 53. In fact, Edwards et al. explains at column 7, lines 48-51 that, in such embodiment, the "stylet 54" comprises "a solid core needle 56" that is coaxially positioned within the tube. As explained above, it is the tip of that "solid core" needle 56 that penetrates into tissue. Edwards et al. does not disclose or suggest any capability of the sleeve 60 or tube 58 to penetrate tissue without the solid core needle 56 being in place. Thus, neither the sleeve 60 nor tube 58 of Edwards et al. can possibly satisfy the claimed limitation of "a tissue penetrating element having a lumen, a tissue penetrating distal tip and a distal end opening."

Moreover, Edwards, et al. id completely devoid of any disclosure of a guidewire as recited in Appellants' claim 53. As noted above, Appellants' independent claim 53 specifically recites

"a guidewire that is advanceable through the lumen of the tissue penetrating element while the tissue penetrating element is in the second position." In contrast, the Edwards et al. device is used to deliver ablative energy to the prostate gland and does not include any guidewire or anything that serves the function of a guidewire. Indeed, there would be no motivation to modify the Edwards, et al. device to include a guidewire because Edwards et al. does not describe or suggest any desire to guide other apparatus into the prostate gland after the ablative energy has been delivered. There is simply no reason or motivation given to insert a guidewire or to leave any guidewire in place after the device is removed.

In the final office action, the Examiner contends that the items identified by Edwards et al. reference numerals 56 and 66 are guidewires. This is not correct. As explained above, reference numeral 56 refers to a "solid core needle" not a guidewire (col.7, line 48). Also, reference numeral 66 refers to a structure that is alternately termed a "conductive needle wire" (col.8, line 9) or a "needle antenna." (col. 8, line 17). Edwards et al. contains no disclosure or suggestion that any of these structures could be left ion place after the remainder of the device has been removed or that any other apparatus could or should be advanced over or "guided" by these structures.

In the Advisory Action, the Examiner dismissed Appellant's arguments for patentability. Specifically, the Examiner stated in the Advisory Action that "the device and elements as disclosed by Edwards, et al. are configured such that there is a tubular member

having a lumen and a distal end opening, moreover the tip of the tube does penetrate tissue as shown in figure 7 and therefore may be construed as a tissue penetrating tip as broadly claimed by applicant."

In reality, Figure 7 of Edwards et al. (reproduced below) does not show any penetration into tissue.

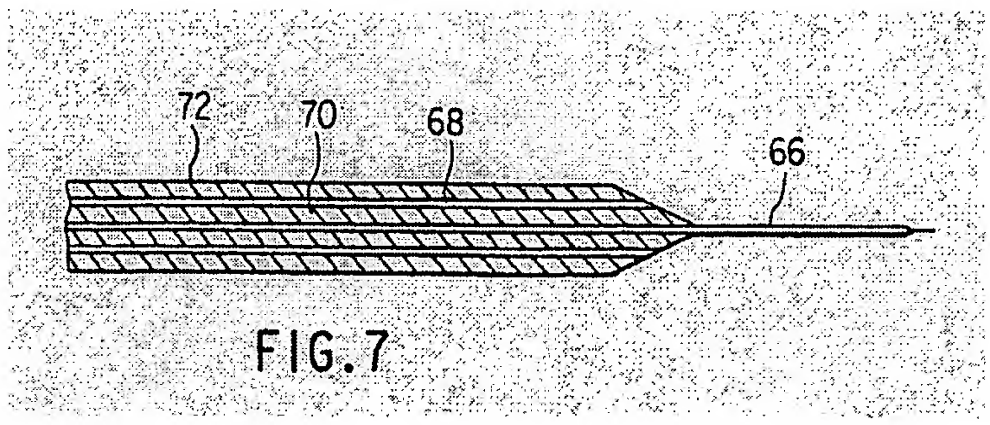


FIG.7

Rather, Figure 7 of Edwards et al. is a cross-sectional representation of a particular "microwave antenna stylet." (Col. 4, lines 54-56) This microwave antenna stylet comprises a "central conductive wire needle 66 with a surrounding conductive wire mesh or tube, the space therebetween being filled with a conventional dielectric solid 70." (Col. 8, lines 8-12) This is described a unitary structure. It may be insertable into tissue, but it clearly lacks the lumen, distal end opening and moveable guidewire required by Appellants' claim 53.

Thus, the system recited in claim 53 is not anticipated by Edwards et al. and the stated rejection of claim 53 is improper and not sustainable.

B. The Rejection of Claim 54 is improper and not sustainable

Dependent claim 54 further limits the system of claim 53 by requiring the system to include an anchoring member that is "deployable when the catheter body is inserted into an anatomical lumen such that a surface of the anchoring member will engage a wall of the anatomical lumen thereby preventing at least a portion of the catheter body from undergoing substantial movement within the anatomical lumen." In the final office action, this claim was rejected over the combination of Edwards et al. and Shturman.

Dependent claim 54 is allowable for all of the reasons stated above with respect to independent claim 54. Although Edwards, et al. Figure 4 shown annular balloons 30, 32 that may be used to stabilize the probe and dilate the urethra, the Edwards, et al. disclosure remains devoid of any teaching of or motivation to include the claimed guidewire. Furthermore, neither Edwards et al. nor Shturman contain anything that would motivate anyone to combine them in the manner suggested by the Examiner. Such combination was obviously arrived in an attempt at hindsight reconstruction. Moreover, even if the teachings of Edwards et al. and Shturman were combined, such would not render obvious the invention claimed in claim 54.

Shturman describes an inflatable sheath that may be passed through an endoscope to a position within a body lumen. An ultrasonic imaging device is inserted into the sheath and the sheath is inflated with ultrasound coupling medium such that the walls of the inflated sheath contact the walls of the body lumen in

which it is positioned. The purpose of the sheath inflation is to provide a continuous coupling medium that allows the ultrasonic imaging device to be used to obtain clear image the surrounding tissues. The inflated sheath does not anchor the ultrasonic imaging catheter. The imaging catheter remains moveable within the inflated sheath.

Furthermore, the Shturman device does not include any apparatus useable to penetrate into or through the wall of the body lumen or to deliver any guidewire to any location outside the body lumen.

C. The Rejection of Claim 55 is improper and not sustainable

Dependent claim 55 further limits claim 54 by requiring the anchoring member to comprise a balloon. Claim 55 is also rejected over the Edwards, et al.-Shturman combination. Thus, claim 55 is allowable for all of the reasons stated above with respect to claims 53 and 54. Furthermore, the inflatable sheath of Shturman is not an balloon that prevents "at least a portion of the catheter body from undergoing substantial movement within the anatomical lumen" as required in claim 55. Rather, Shturman describes a sheath that is entirely filled with ultrasonic coupling agent and within which an ultrasound imaging catheter remains unanchored and moveable within the body lumen.

D. The Rejections of Claims 56 and 57 are improper and not sustainable

Dependent claim 56 depends from claim 54 and requires the

inclusion of a friction enhancing treatment upon a surface of the anchoring member. Claim 57 depends from claim 56 and and requires the friction enhancing treatment to be selected from the group consisting of texturing, adhesive and woven fabric.

Claims 56 and 57 are rejected over the combination of Edwards, et al. and Shturman as applied to claim 54 and further in view of Aberle et al. Aberle et al. describes balloon catheters s that have areas with differing coefficient's of friction. When the balloon is deflated, the areas having the higher coefficient of friction are in-folded so that they are not exposed to adjacent structures. When inflated, the balloon unfolds, thereby allowing the areas having the higher coefficient of friction to contact the adjacent surface. However, the catheters of Aberle et al. do not include any tissue penetrating element that could be used to penetrate into or through the wall of the body lumen in which the catheter is positioned nor does Aberle et al. disclose any means or desire to deliver any guidewire to a location outside the body lumen in which the catheter is positioned. Thus, even if Aberle et al. were combined with Edwards, et al;. and Shturman, the combination would still be lacking of the required guidewire. Furthermore, there is no suggestion in Edwards, et al. that slippage or movement of the inflated sheath is a problem. Thus, absent hindsight, there exists no motivation to combine Aberle, et al. with Edwards et al. and Shturman.

E. The Rejection of Claim 58 is improper and not sustainable

Dependent claim 58 depends directly from independent claim 53

and requires the catheter device to additionally comprise "a lumen within the catheter body to receive an imaging apparatus." In the final office action, dependent claim 58 was rejected as being anticipated by Edwards, et al.

Edwards, et al. contains no disclosure of any lumen that would reasonably be useable to receive an imaging device. Furthermore, Edwards, et al. specifically teaches away from the insertion of an imaging device into the transurethral probe by utilizing a transrectal imaging probe (item 18 on Edwards, et al. Figure 1) that is inserted into a separate body lumen. Clearly claim 58 is not anticipated (or even rendered obvious) by Edwards, et al. This rejection cannot be sustained.

F. The Rejections of Claims 61 and 62 are improper and not sustainable

Claim 61 depends from claim 58 and affirmatively recites the inclusion of an imaging device within that lumen. Thus, dependent claim 61 is directed to a system that generally includes a catheter device that includes a tissue penetrating element, a guidewire that is advanceable through the tissue penetrating element and an imaging device. Claim 62 depends from claim 61 and requires the imaging device to comprise an intravascular ultrasound imaging device.

In the final office action, claims 61 and 62 are rejected over the combination of Edwards, et al. in view of Shturman. In support of this rejection, the final office action makes reference to Shturman's Figure 15, column 3, lines 60+ and column 6, lines 50+.

With respect to claims 61 and 62, Appellant restates the arguments set forth above with respect to claims 53, 54 and 58. Even if the Edwards, et al. and Shturman were to be properly combined, the resultant combination would still lack the claimed guidewire element and imaging apparatus receiving lumen.

F. The Rejection of Claim 63 is improper and not sustainable

Claim 63 depends from claim 58 and specifies that the penetrating element is advanced from a first lumen of the catheter body and an imaging apparatus is received in a second lumen of the catheter body. In the final office action claim 63 was rejected over Edwards et al. in view of Shturman and further in view of Seward et al.

With respect to claim 63 Appellant restates and incorporates the arguments set forth above with respect to claims 53 and 58. Furthermore, Seward, et al. describes self contained catheters that have ultrasound devices that have ultrasound transducers 30, 100 mounted within the catheter, not separate imaging apparatus receiving lumens adapted to receive separate imaging catheters. Also, Seward, et al. discloses no tissue penetrating mameber that has a lumen and distal end opening through which a guidewire may be advanced to a target location outside of the body lumen in which the catheter is positioned.

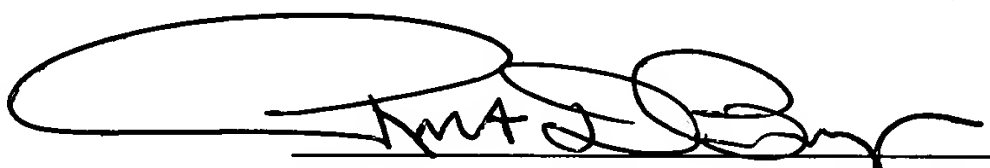
Moreover, absent hindsight, there is no teaching or suggestion in any of these references that would motivate one to combine these

three references in the manner suggested in the final office action.

IX. CONCLUSION

On the basis of the arguments and authorities set forth hereabove, Appellant respectfully submits that claims 53-58 and 61-63 are in condition for allowance over all prior art of record. Appellant requests that the Board reverse the rejections of claims 53-58 and 61-63 and order that a Notice of Allowance be issued with respect to such claims.

Respectfully submitted,
STOUT, UXA, BUYAN & MULLINS, LLP

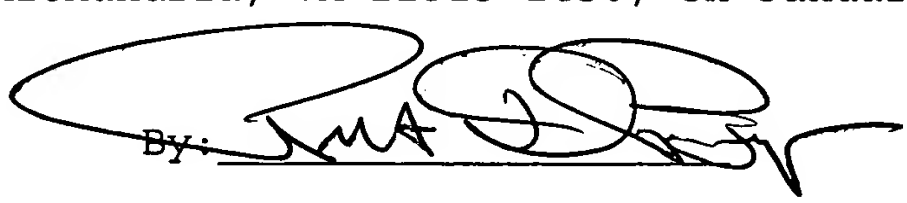


Robert D. Buyan, Reg. No. 32,460
Date: January 18, 2006
4 Venture, Suite 300
Irvine, CA 92618
Telephone: (949) 450-1750, Facsimile: (949) 450-1764
email: rbuyan@patlawyers.com

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: MAIL STOP APPEAL BRIEF-PATENTS, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on January 18, 2006.

Date: January 18, 2006 By:



Robert D. Bunyan, Reg. No. 32,460

X. APPENDIX OF CLAIMS

EXHIBIT A

Claim 1 - 52 (canceled)

Claim 53 (previously amended) A system that is useable to guide the advancement of a guidewire from a location within the lumen of a blood vessel to a location within or outside of the wall of that blood vessel, said system comprising:

a elongate catheter body that is advanceable into said blood vessel lumen, said catheter body having at least one lumen extending longitudinally therethrough;

an opening formed in said catheter body;

a tissue penetrating element having a lumen, a tissue penetrating distal tip and a distal end opening, said tissue penetrating element being alternately disposable in;

a) a first position wherein the tissue penetrating element is substantially within the catheter body; and

b) a second position wherein the tissue penetrating element assumes a predetermined curved configuration and extends out of the opening so as to penetrate a wall of the blood vessel adjacent to the blood vessel lumen in which the catheter is positioned; and

a guidewire that is advanceable through the lumen of the tissue penetrating element while the tissue penetrating element is in the second position.

Claim 54 (previously amended) A system according to claim 53 further comprising an anchoring member, said anchoring member being deployable when the catheter body is inserted into an anatomical lumen such that a surface of the anchoring member will engage a wall of the anatomical lumen thereby preventing at least a portion of the catheter body from undergoing substantial movement within the anatomical lumen.

Claim 55 (previously amended) A system according to claim 54 wherein the anchoring member comprises a balloon.

Claim 56 (previously amended) A system according to claim 54 further comprising a friction enhancing treatment upon a surface of the anchoring member.

Claim 57 (previously added) A system according to claim 56 wherein said friction enhancing treatment is selected from the group of friction enhancing treatments consisting of:

texturing;

adhesive; and,

woven fabric.

Claim 58 (previously amended) A system according to claim 53 further comprising a lumen within the catheter body to receive an imaging apparatus.

Claim 59 (cancelled)

Claim 60 (cancelled)

Claim 61 (previously amended) A system comprising a device according to claim 58 in combination with an imaging apparatus positioned with said lumen adapted to receive an imaging apparatus.

Claim 62 (previously amended) A system according to claim 61 wherein the imaging apparatus comprises an intravascular ultrasound imaging apparatus.

Claim 63 (previously amended) A system according to claim 58 wherein the catheter body has a first lumen from which the tissue penetrating element is advanced and a second lumen for receiving the imaging apparatus.